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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/180,132	05/24/1999	HYUN K. KIM	15280-261004	6445

7590 12/19/2002

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EXAMINER

BADIO, BARBARA P

ART UNIT	PAPER NUMBER
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1616

DATE MAILED: 12/19/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/180,132

Applicant(s)

KIM ET AL.

Examiner

Barbara P. Badio, Ph.D.

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-36 is/are pending in the application.
- 4a) Of the above claim(s) 3,8-14,20-25 and 28-36 is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1,2,4-7,15-19,26 and 27 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on ____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. ____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). ____. |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) ____. | 6) <input type="checkbox"/> Other: _____ |

Supplemental Non-Final Office Action on the Merits

1. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Double Patenting

2. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

3. Claims 1, 2, 4-7, 15-19, 26 and 27 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-9, 21-25, 29, 33-38, 40-42 and 46-60 of copending Application No. 09/526,855. Although the conflicting claims are not identical, they are not patentably distinct from each other because they are both drawn to 21-substituted progesterone derivatives. The difference between the claimed inventions is in the scope of the compounds recited therein. For example, copending Application No. 09/526, 855 recites compounds wherein R₂ is hydrogen whereas the present application does not.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claim Rejections - 35 USC § 103

4. The rejection of claims 1, 2, 4-7, 15-19, 26 and 27 under 35 USC 103(a) over Torelli et al. ('695) is maintained.

Applicant argues (a) the reference does not teach or suggest the claimed compounds, (b) the only compound that arguably fell within the scope of the claimed invention is used as an intermediate to form the claimed compounds and (c) the compounds taught by the reference possess different properties and, thus, different utilities than the claimed compounds. Applicant's arguments were considered but not persuasive for the following reasons.

As indicated in the previous Office Action, the utility of the claimed compound(s) is irrelevant to the patentability of the compounds. The issue is whether the prior art provides motivation to make and/or use the compounds as claimed. Torelli teaches a genus of compounds that encompasses the claimed compounds and provides motivation to make the claimed compounds. The motivation is based on the teaching by the reference of numerous compounds having a 17 β -acyl group and an 11-dimethylaminophenyl group as recited by the instant claims. The difference between the compounds exemplified by the prior art and the claimed compound(s) is the 17 α substituent exemplified by the prior art. However, each of the 17 α groups recited by the instant claims are disclosed by the reference and, thus, the reference teaches an

equivalence between each of applicant's recited 17α substituents. Therefore, substituting one group for the other would be prima facie obvious. The motivation to interchange the groups is based on the teachings of the reference that the compounds produced would have similar activities as taught for the genus by Torelli.

Applicant also argues the prior art compounds possess different properties and, thus, different utilities than the claimed compounds because it possesses minimal antiglucocorticoid activity. If applicant is arguing unexpected and unobvious results, applicant has not provided any factual evidence in support. In the absence of said evidence, applicant's argument is not persuasive because like the claimed compounds, the prior art compounds have antiprogestomimetic as well as anti-glucocorticoid activities. The ordinary artisan in the art would have the reasonable expectation that these properties would vary between compounds.

For these reasons and those given in previous Office Actions, the rejection of 1, 2, 4-7, 15-19, 26 and 27 under 35 USC 103(a) over Torelli et al. ('695) is maintained.

Other Matters

5. Applicant's supplemental response and Declaration filed August 9, 2002 are noted. However, it should be noted that the Declaration does not address the rejection over Torelli as discussed above. In applicant's supplemental response, it is pointed out that Dr. Kim's declaration states the present application provides activity data showing the activity of selected compounds. Applicant states that the compounds of Torelli unlike the claimed compounds possess substantial antiglucocorticoid activity. However,

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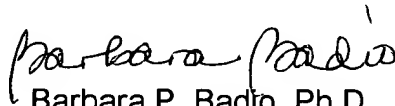
the data referred to by applicant does not include a comparison of the prior art compound as exemplified by Torelli (see compound 9, figure 1 of the present application) and, thus, applicant's argument is not persuasive. The examiner notes that any comparison should be commensurate in scope with the claimed invention.

Telephone Inquiry

6. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Barbara P. Badro, Ph.D. whose telephone number is 703-308-4595. The examiner can normally be reached on M-F from 7:30am-4pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jose Dees can be reached on 703-308-4628. The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-4556 for regular communications and 703-308-4556 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1235.


Barbara P. Badro, Ph.D.
Primary Examiner
Art Unit 1616

BB
December 18, 2002